

**Putney, Rebecca M.**

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**From:** Patskan, George J.  
**Sent:** Wednesday, August 30, 2000 4:20 PM  
**To:** Richard Carchman (E-mail); Solana, Rick P.; Haussmann, Hans J.; Reininghaus, Wolf; Sanders, Edward; Davies, Bruce D.; Koller, Debbie; Tricker, Anthony; Dempsey, Ruth; Walk, Roger A.; Takada, Kohji; Terpstra, Piter; Cox, Richard H.; Roemer, Ewald; Elves, Robert G.; Compton, David A.; Edward Carmines; Gerry Nixon; Michael Werley  
**Cc:** Bugg, Joy J.; Viol, Brigitte; Cash, Rose B.  
**Subject:** Harm reduction meeting - Sep 19-20

The meeting on Harm Reduction has been scheduled for Sep 19 and 20 and will take place in the Richmond area.

The purpose of the meeting is to bring together the ideas that we've been talking about that relate to harm reduction so that we can make sure we have a reasonably coordinated effort and can begin planning projects and activities. One way of looking at this is what do we really know because we have solid data, from this what guidance can we give to product development folks today (or in the near future), and then what do we need to know (including how to measure certain things) to do a better job of harm reduction in the future.

The following proposed agenda has been drafted using the original agenda and comments received. Please let me know if you have comments or suggestions.

I view the people listed by each topic not as presenters so much as discussion leaders. Presentations can be as detailed as people would like. My suggestion is to provide a summary of the appropriate background information as a basis for further discussion. The objective for each section would be what do we know, and where do we need to go in that area. I'm not sure whether it is best to talk about guidance as we go or at the end. Right now I'm planning for it at the end.

I think that we should put on our 10X vision glasses for this meeting. We've come a long way over the course of this year with harm reduction ideas I think mainly because we were willing to go beyond our typical way of viewing things; we need to continue that approach. We also need to make sure that what we do in the area of harm reduction is grounded firmly in solid science.

**Draft Agenda:**

- What are the goals for harm reduction? (Patskan) [1hr]  
What is the definition for harm reduction?  
How do we determine what diseases to focus on?  
What are the criteria for success?  
Are we looking at individuals or populations?  
Is this the same everywhere in the world?  
ETS?
- Fundamental understanding of diseases associated with smoking:  
What disease endpoints should we focus on? [1.5 hr]  
From IOM: Lung cancer, Cardiovascular disease, COPD  
Repro/Developmental (Dempsey, Carmines)  
Mechanisms of those diseases? What do we know? What do we need to know?
- Testing/endpoints:  
Smoke chemistry (Patskan, Haussman) [1hr]  
in vitro/in vivo biological testing (INBIFO) [1hr]  
human exposure assessment (Walk) [1hr]  
human biomarkers of effect (Tricker) [1hr]  
epidemiology (Sanders) [1hr]  
For all of these I think the discussion should be about how the endpoint measured relates to the diseases from above.  
What can we measure today? What new endpoints should we measure?
- Smoking behavior (Davies, Takada) [1hr]
- Approaches for data analysis, interactions fractals, chaos (Carchman) [1hr]

- Gnomics/Proteomics/Gene expression (Koller) [0.5hr]
- Guidance (Patskan) [2hr]  
Based on what we know today what guidance can we provide product development?  
How much of a reduction in the activity or yield is significant?  
What information do we have about what design features drive certain biological activities?  
Communication of risk (Koller)  
Index  
Regulatory involvement

As I said before:

I'm not suggesting that we pull out all the information we have about these topics to do a review; that could take years. I think that we should have enough information so that we can discuss what is that we already clearly know about how to proceed in the realm harm reduction and what areas do we need to develop.

Attendance: By sending this message to certain people I don't mean to exclude others who might want to attend and can make a significant contribution to this effort, so please invite others as appropriate.

Please let me know your comments and suggestions.

Thanks,  
George